Novan Announces First Patient Dosed in Phase 2 Anti-Fungal Program

Top-Line Results Expected in First Half of 2017

DURHAM, N.C. – July 21, 2016 – Novan, Inc. today announced that the first patient has been dosed in the Company's Phase 2 clinical program to evaluate the efficacy and safety of topical nitric oxide product candidate SB208 in the treatment of infections caused by dermatophytes such as *Trichophyton rubrum* ("*T. rubrum*"). Novan is developing SB208 as a broad-spectrum anti-fungal gel for the treatment of infections of the skin and nails, including athlete's foot and onychomycosis.

"Initiating our Phase 2 program for SB208 represents another important milestone for Novan in the development of our nitric oxide platform," said Nathan Stasko, PhD, President and Chief Executive Officer of Novan. "It also represents our next example of taking a fundamental nitric oxide mechanism of action, generating compelling preclinical evidence and then translating that success into a clinical-stage product candidate. In view of the FDA's recently repeated warning about the use of oral ketoconazole to treat skin and nail fungal infections,[1] we believe that physicians and their patients deserve a new fungicidal therapy with an attractive safety profile. This study aims to demonstrate activity of topical SB208 against key pathogens like *T. rubrum* in athlete's foot before broadening the program to assess treatment of other fungal infections."

This Phase 2 clinical trial is a multi-center, double-blind, randomized, vehicle-controlled, dose-ranging study to determine the dose of SB208 that achieves maximum anti-fungal activity with a favorable safety and tolerability profile. Approximately 170 patients with athlete's foot will be randomized to either SB208 Gel (2%, 4% or 16%) or vehicle and treated once daily for two weeks. Endpoints at week two and following a four-week post-treatment observation include assessments of mycological, clinical and overall therapeutic cure, which includes both mycological and clinical cure. Novan expects to report top-line results of this Phase 2 trial in the first half of 2017.

In June at ASM Microbe 2016, Novan presented data from preclinical studies demonstrating anti-fungal activity of the Company's nitric oxide-releasing candidates against *T. rubrum*. *In vitro* studies included evaluation of anti-fungal activity utilizing the ChubTur® infected human nail assay, a model utilized previously in the drug development of Kerydin® (tavaborole) Topical Solution, 5%,[2] and Jublia® (efinaconazole) Topical Solution, 10%.[3] In this assay, *T. rubrum* was inoculated to the underside of human nails and allowed to establish infection. Several of Novan's nitric oxide-releasing formulations were applied topically to the top of the infected nail plates to assess nail penetration and anti-fungal activity. All of the tested formulations demonstrated effective fungal killing on the underside of the nail in 24 hours following a single treatment application. The poster presentation describing this work is available on the Company's website at www.Novan.com.

About Novan

Novan, Inc. is a late-stage specialty biotechnology company focused on redefining the standard of care in dermatology through the development and commercialization of innovative therapies using the Company's nitric oxide platform. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate

differentiated, first-in-class product candidates. We are rapidly advancing programs in five dermatological conditions with significant unmet medical need. We believe that our ability to conveniently deploy nitric oxide on demand in topical formulations allows us the potential to significantly improve patient outcomes in a variety of skin diseases and positions us to be a commercially successful leader in the dermatology market.

For more information, visit the Company's website at www.Novan.com.

Forward-Looking Statements

This press release contains forward-looking statements including, but not limited to, statements related to pharmaceutical development of nitric oxide-based product candidates and future prospects. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from our expectations. These forward-looking statements speak only as of the date of this press release, and Novan disclaims any intent or obligation to update these forward-looking statements, except as expressly required by law.

References

[1] U.S. Food and Drug Administration. "FDA Drug Safety Communication: FDA warns that prescribing of Nizoral (ketoconazole) oral tablets for unapproved uses including skin and nail infections continues; linked to patient death." http://www.fda.gov/Drugs/DrugSafety/ucm500597.htm (July 19, 2016).
[2] Coronado D, Merchant T, Chanda S, Zane L. In Vitro Nail Penetration and Antifungal Activity of Tavaborole, a Boron-Based Pharmaceutical. J Drugs Dermatol. 2015; 14(6):609-614.
[3] Sugiura K, Sugimoto N, Hosaka S, Katafuchi-Nagashima M, Arakawa Y, Tatsumi Y, Jo Siu W, Pillai R. Efinaconazole: low keratin affinity contributes to nail penetration and fungicidal activity in topical onychomycosis treatment. Antimicrob Agents Chemother. 2014 Jul; 58(7):3837-42.

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